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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,635	06/08/2001	James N. Herron	3278.2US	9774

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/877,635	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The grant of the petition to withdraw the holding of abandonment is noted, and the holding of abandonment on September 27, 2005 is hereby vacated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-30, 32, 33, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt, 4,849,340, in view of Jackowski, 5,747,274.

Oberhardt discloses the invention substantially as claimed. Oberhardt discloses an assay system comprising: a waveguide (27) configured to generate an evanescent field (col. 22, lines 27-31) over at least one planar surface having capture molecules (col. 22, lines 29-31);

a light source (120) positioned to direct light into said waveguide;

fluorescently labeled tracer molecules that indicate binding (col. 22, line 29-31); a light detector (121) for detecting fluorescent light passed through said planar surface and an opposite surface of said waveguide and emitted when said fluorescently labeled tracer molecules are excited by the evanescent field (col. 22, lines 14-18, and 38-49);

said light detector being capable of generating an intensity signal indicating an intensity of said detected light (col. 11, line 12);

and a controller (i.e., processor 182, col. 18, line 16, and col. 19, lines 27-41) for monitoring said intensity signal and being capable of correlating said intensity signal to a concentration of at least one indicator of coronary artery disease in the sample.

Oberhardt teaches that the system is used for assays utilizing immobilized molecules for binding to molecules in samples, the assay being analyzed with a fluorescence detector, (col. 22, lines 29-31; see also col. 29, lines 40-43, col. 30, lines 15-16.)

However, Oberhardt does not specifically disclose that the capture molecules on the planar surface is for capturing at least one indicator of coronary artery disease, as recited by Applicants in claim 21.

As to claim 23, Oberhardt does not disclose that the capture molecules include capture molecules that bind with at least a portion of at least one of a troponin, creatine kinase, or myoglobin molecule or complex.

As to claim 32, Oberhardt does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one ischemic marker or at least one complex that includes at least one ischemic marker.

As to claim 33, Oberhardt does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one marker released from cardiac tissue only after a myocardial infarction or at least one complex that includes marker released from cardiac tissue only after a myocardial infarction.

Jackowski teaches these limitations by teaching an assay system comprising immobilized molecules, a waveguide, see column 27, line 47 – column 28, line 11, and column 29, lines 1-31, and fluorescence detector, see column 28, lines 12-38. In addition, Jackowski teaches use of capture molecules (specifically antibodies, col. 19, lines 15-18) that bind with troponin, creatine kinase, or myoglobin (see column 4, lines 35-36, and column 5, lines 29-31), for the detection of myocardial infarction (see column 4, lines 32- column 8, line 31, and column 19, lines 8-14, and column 29, lines 51-63, and column 29, lines 51-63, and column 22, lines 1-12), wherein the capture molecule is immobilized on a waveguide surface (see column 27, lines 38-58, and column 29, lines 1-27.) Moreover, Jackowski teaches that the capture molecules can be used in various techniques available in optical sensor technology (see column 29, lines 28-31), and also lists evanescent field fluorescence detection as an example (col. 27, lines 18-20.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the capture molecules for the detection of myocardial infarction taught by Jackowski as the specific types of capture molecules on the Oberhardt waveguide since Jackowski teaches that such capture molecules provide the benefit of detecting myocardial infarction and can be utilized with known optical sensor technology. That is, the skilled artisan would have been motivated to use the capture molecules taught by Jackowski using the Oberhardt waveguide because Jackowski teaches that such molecules provide the benefit of detecting myocardial infarction, as would be desirable to prevent a medical problem. Moreover, Jackowski suggests utilizing known evanescent field fluorescence detection techniques, which would also

motivate the skilled artisan to utilize the Jackowski capture molecules with the specific evanescent field fluorescence detection system disclosed by Oberhardt. Moreover, since both the Oberhardt assay and the Jackowski assay are binding assays using fluorescence detection, and Jackowski teaches that the disclosed assays can be performed utilizing known optical sensor technology, and the Oberhardt waveguide is a known optical sensor technology, the skilled artisan would thus have reasonable expectation of success in using the Jackowski antibodies as the specific types of capture molecules for performing a binding assay using the Oberhardt device.

As to claim 22, said waveguide is optically associated with a rear lens (191) oriented for reading light from said light source passing through said waveguide, to monitor coupling efficiency and beam quality. (Although element 191 is described as a second external waveguide in column 22, line 42, it is considered a lens since it is a transparent material used in forming an image. Element 191 is considered to be capable of allowing the monitoring of coupling efficiency and beam quality since it allows light ray 40 to pass through and be monitored by detector 121—see col. 22, lines 40-42.)

As to claim 24, said at least one reaction area comprises a reservoir (containing reaction volume 66, col. 22, lines 28-29.)

As to claim 25, said at least one reaction area comprises a well (see fig. 29.)

As to claim 26, said controller (i.e., processor 182) is capable of correlating in a substantially continuous fashion (since it is disclosed as being used to monitor assay kinetics, col. 19, lines 33-43.)

As to claims 27 and 29, Oberhardt discloses a controller (i.e., microprocessor 182) which receives the resultant digital information of the detection and monitors assay kinetics (col. 19, lines 29-41). As to the limitation regarding the detection of coronary artery disease, i.e., correlation until a reliable determination of the presence of an indicator in an amount indicative of coronary artery disease, Oberhardt discloses that the concentration of analyte can be determined from the fluorescent signal (see for example, col. 23, lines 16-22), and thus in combining the teachings of Oberhardt and Jackowski, the skilled artisan would have modified the microprocessor of Oberhardt such that it is capable of detecting a certain level of markers, i.e., concentration, of coronary artery disease in order to determine the presence of a coronary artery disease as taught by Jackowski.

As to claims 28 and 30, said controller (182) is capable of being configured to output a signal that effects reporting of said reliable determination (col. 19, lines 33-41.)

As to claim 45, the at least one planar surface (10) of the waveguide comprises optical plastic (col. 15, line 23.)

As to claim 46, the system further comprises a first member (30, see figure 29) associated in liquid tight attachment with said at least one planar surface of said waveguide, wherein said first member, in conjunction with said waveguide, defines at least one reaction area for containing the biological liquid sample while said at least one planar surface of said waveguide defines a floor or ceiling of said at least one reaction area (see figure 29, and col. 22, lines 25-29.)

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt, 4,849,340, in view of Jackowski, 5,747,274, or alternatively over Oberhardt, 4,849,340, in view of Jackowski, 5,747,274, as applied to claim 21 above, and further in view of Brosnan et al., 4,987,086.

As to claim 31, Oberhardt disclose a controller (i.e., microprocessor 182) which receives digital information from the detector and monitors assay kinetics in col. 19, lines 33-41). Moreover, Oberhardt disclose in column 22, in lines 14-18, an embodiment to perform fluorescent evanescent wave measurements near a wall and simultaneous with colorimetric or fluorescent measurements through the reaction volume. Moreover, Jackowski teach simultaneously assessing the level (i.e., concentration) of a plurality of markers of coronary artery disease (col. 10, line 19-26). Jackowski teach use of labels including fluorescent labels (col. 23, line 55 and col. 24, line 39). It is understood that the labels are different such that they can be simultaneously detected and measured. Thus, in the combination of the references, as discussed above regarding claim 21, the skilled artisan would also utilize different fluorescent labels, as is understood from the reading of the Jackowski reference, in order to simultaneously detect analytes as taught by Jackowski utilizing the device taught by Oberhardt.

Alternatively, Oberhardt in view of Jackowski disclose the invention substantially as claimed (see above regarding claim 21). More specifically, as to claim 31, Oberhardt disclose a controller (i.e., microprocessor 182) which receives digital information from

the detector and monitors assay kinetics in col. 19, lines 33-41). Moreover, Oberhardt disclose in column 22, in lines 14-18, an embodiment to perform fluorescent evanescent wave measurements near a wall and simultaneous with colorimetric or fluorescent measurements through the reaction volume. Moreover, Jackowski teach simultaneously assessing the level (i.e., concentration) of a plurality of markers of coronary artery disease (col. 10, line 19-26). Jackowski teach use of labels including fluorescent labels (col. 23, line 55 and col. 24, line 39). However, neither Oberhardt nor Jackowski specifically teach the use of different labels for the simultaneous detection of analytes.

Brosnan teach fluorescent labels which have emission spectra with sufficient wave length separation to permit simultaneous detection of two or more colors, such as phycoerythrin, which emits fluorescence at 570 nm and fluorescein isothiocyante which emits at 530 nm, and both are excited at 488 nm wavelength (col. 6, lines 51-68.) Given the teachings of Jackowski of simultaneous detection of analytes using various techniques available in optical sensor technology (see column 29, lines 28-31), including evanescent field fluorescence detection (col. 27, lines 18-20), the skilled artisan would have looked to the art to find specific means for providing simultaneous detection, such as the specific teachings of utilizing different fluorescent labels as taught by Brosnan et al. That is, while Jackowski disclose simultaneous detection of analytes but do not specifically disclose use of different fluorescent labels, the skill artisan would look to the art for specific teachings in the art on such detection, for example, teachings on how the different analytes are distinguished from each other, such as use of different fluorescent labels taught by Brosnan et al. Moreover, the skilled artisan would have

reasonable expectation of success in combining the teachings of the three references because all three references teach fluorescence detection and Jackowski further teach simultaneous detection and thus the skilled artisan would have reason to expect that multiple fluorescent labels disclosed by Brosnan et al. can be detected using the Oberhardt waveguide. Furthermore, given the desirability of simultaneous detection disclosed by Jackowski and Brosnan et al., the skilled artisan would have been motivated to also modify the controller (microprocessor) of Oberhardt to simultaneously analyze the detection, as such simultaneous analysis would also provide the benefit of convenience.

Response to Arguments

Applicants' arguments filed November 13, 2006 have been fully considered.

Applicants have amended claim 21 to clarify the language but assert that the unamended claim 21 complied with 112, second paragraph. Examiner agrees that claim 21 should not have been held to be indefinite, and that claim 21 as presently amended or as recited previously comply with 112, second paragraph.

The remainder of Applicants' arguments however are not persuasive.

Applicants argue on page 6 that in the Oberhardt invention the radiation that is detected by detector (121) is positioned on a side opposite of base (30) but on the same side of the waveguide (1) as the reaction volume (66), pointing to figure 29 and column 22, lines 14-37, and thus the fluorescent radiation that is detected does not pass

through any part of the waveguide. This is not persuasive because there is also disclosed in figure 29, another waveguide (27), and a second detector (121) wherein the radiation (41) passes through the waveguide from one side of the waveguide to the opposite side of the waveguide and to detector (121). This is also disclosed in column 22, lines 14-18, and 38-49. That is, while Applicants point to one embodiment disclosed by Oberhardt, Examiner relies on another embodiment disclosed by Oberhardt, which is the same invention as that claimed by Applicants.

Applicants also argue on page 6 that Oberhardt teaches that fluorescent radiation that passes directly through a waveguide (30) may be detected by a detector (121) positioned adjacent to an opposite surface of the waveguide (30) from the surface that is exposed to a sample (66), but these teachings are limited to situations where fluorescent radiation of relatively high intensity occurs, pointing figure 30, column 22, line 56 to column 23, line 39. Applicants assert that the only example provided by Oberhardt is in determining hematocrit, where large quantities of the fluorescent dye are merely adsorbed to a surface of the waveguide, some of the fluorescent dye dissolves in the plasma of a blood sample, and fluorescence is measured to provide an indication of the amount of dye that remains on the surface of the waveguide (30) as well as an indication of the hematocrit (i.e., percentage of red blood cells) of the blood sample. Examiner however does not find this argument to be persuasive for the following reasons. Examiner does not find that Oberhardt limits the embodiment recited by Applicants to situations where fluorescent radiation of relatively high intensity occurs, as there is no such disclosure or suggestion by Oberhardt. Secondly, Applicants point to

the embodiment of figure 30 disclosed by Oberhardt presumably because it discloses a detector that is positioned adjacent to an opposite surface of the waveguide (30) from the surface that is exposed to a sample. However, this embodiment is not relied upon by Examiner nor is it claimed by Applicants. Applicants recite in claim 21, lines 9-12, "a light detector for detecting fluorescent light passed through said planar surface and an opposite surface of said waveguide and emitted when said fluorescently labeled tracer molecules are excited by the evanescent field". Thus, Applicants recite a detector that is capable of detecting fluorescent light passed through one surface to an opposite surface of the waveguide, rather than a detector that is positioned adjacent to an opposite surface of the waveguide (30) from the surface that is exposed to a sample. Thus, Examiner relies on the disclosure column 22, lines 14-18, and 38-49, and figure 29, which clearly disclose the invention recited by Applicants.

Applicants also argue on pages 6 to 7 that the description of Jackowski is limited to the use of an optical waveguide-type assay systems in a way that fluorescent signals are discriminated by their angular divergence upon exiting the waveguide. Applicants assert that the measurement of the angular divergence of fluorescent light as it exits a waveguide is the only type of detection taught by Jackowski. Examiner does not find this argument persuasive because the Jackowski reference is relied upon in the grounds for rejection only for its teaching of antibodies that detect markers of myocardial infarction rather than on the teachings of a waveguide detection system, which is only disclosed generally. Jackowski teaches that the assay can be performed using various techniques available in optical sensor technology (see column 29, lines

28-31), and also lists evanescent field fluorescence detection as an example (col. 27, lines 18-20). There is nothing in the disclosure of Jackowski that would suggest that the Jackowski immunoassay cannot be utilized with the waveguide and detection system of Oberhardt. To the contrary, Jackowski suggests utilizing known evanescent field fluorescence detection techniques, which would motivate the skilled artisan to utilize the disclosed antibodies with the particular evanescent field fluorescence detection system disclosed by Oberhardt.

Applicants argue on page 7 to 8 that neither Oberhardt nor Jackowski teaches or suggests an assay system that includes a light detector for detecting fluorescent light, from fluorescently labeled tracer molecules, that passes through both a planar surface and an opposite surface of a waveguide. Applicants assert that although Oberhardt teaches that fluorescent radiation may be detected through a waveguide, those teachings are limited to instances where apparently large volumes of dye are used and do not include embodiments in which fluorescently labeled tracer molecules are used to indicate specific binding (e.g., binding of at least one indicator of coronary artery disease with a capture molecule). Applicants assert that the teachings of Jackowksi are limited to discriminating the angular divergence of fluorescent signals as they exit the waveguide through an edge thereof, that is, the fluorescent light enters the waveguide through a planar surface, but does not exit the waveguide through an opposite surface. This appears to be the same argument as previously discussed above, and thus Examiner reiterates that the Jackowski reference is relied upon in the grounds for rejection only for its teaching of antibodies that detect markers of myocardial infarction

rather than on the teachings of a waveguide detection system, which is only disclosed generally and that there is nothing in the disclosure of Jackowski that would suggest that the Jackowski immunoassay cannot be utilized with the waveguide and detection system of Oberhardt. To the contrary, Jackowski suggests utilizing known evanescent field fluorescence detection techniques, which would motivate the skilled artisan to utilize the disclosed antibodies with the evanescent field fluorescence detection system disclosed by Oberhardt.

Applicants assert on page 8 that one of ordinary skill in the art would have no reason to expect that a combination of the teachings of Oberhardt and Jackowski would be successful because neither reference teaches or suggests that fluorescent light emitted from a fluorescent tracer molecule that is used to indicate specific binding between an analyte and a capture molecule may be coupled back into a waveguide through a planar surface, then exit the waveguide through an opposite surface. Examiner however reiterates that such detection is disclosed in column 22, lines 14-18, and 38-49, and figure 29, as illustrated by light ray 40.

Applicants assert at the bottom of page 8 that in view of elements of amended independent claim 21 that are neither taught nor suggested in either Oberhardt or Jackowski, as well as in the lack of a reasonable expectation that the asserted combination of teachings from Foster [it appears that Applicants meant to refer to Oberhardt] and Jackowski, it is submitted that one of ordinary skill in the art would not have been motivated to have combined the teachings of Oberhardt and Jackowski and that any such motivation could only have been improperly gleaned from the disclosure

of the present application. As indicated above, Examiner does not find any elements of claim 21 to not be taught or suggested by Oberhardt or Jackowski, and the reasons for expectation of success have already been discussed above.

Applicants also argue on page 9 that claim 22 is additionally allowable because netiehr Oberhardt nor Jackowski teaches or suggests an assay system that includes a waveguide to monitor coupling efficiency and beam quality. Applicants assert that the disclosure at column 22, lines 18-34 of Oberhardt is limited to use of a first waveguide (190) and prism (202) to introduce light into a cover (waveguide) (10) and a second waveguide (191) and prism (204) to remove light from the waveguide (10). As noted in the grounds for rejection, Examiner points to element (191) as being equivalent to a lens oriented for reading light from said light source passing through said waveguide, to monitor coupling efficiency and beam quality. Although element 191 is described as a second external waveguide in column 22, line 42, it is considered a lens since it is a transparent material used in forming an image. Element 191 is considered to be capable of allowing the monitoring of coupling efficiency and beam quality since it allows light ray 40 to pass through and be monitored by detector 121 (col. 22, lines 40-42.)

Applicants further argue on page 9 that claims 27 and 29 are also allowable since Oberhardt and Jackowski do not reach or suggest a controller which is configured to effect monitoring and correlating until a reliable determination is made of whether at least one indicator is coronary artery disease is present in a sample in an amount indicative of coronary artery disease. As indicated in the grounds for rejection,

Oberhardt discloses a controller (i.e., microprocessor 182) which receives the resultant digital information of the detection and monitors assay kinetics (col. 19, lines 29-41). As to the limitation regarding the detection of coronary artery disease, i.e., correlation until a reliable determination of the presence of an indicator in an amount indicative of coronary artery disease, Oberhardt discloses that the concentration of analyte can be determined from the fluorescent signal (see for example, col. 23, lines 16-22), and thus in combining the teachings of Oberhardt and Jackowski in order to detect the markers of coronary artery disease, as discussed above, the skilled artisan would have also modified the microprocessor of Oberhardt such that it is capable of detecting a certain level of markers, i.e., concentration, of coronary artery disease taught by Jackowski.

Lastly, Applicants argue that claim 31 is additionally allowable since neither Foster [it appears that Applicants meant Oberhardt] nor Jackowski teaches or suggests an assay system that includes a plurality of distinct types of fluorescently labeled tracer molecules, each corresponding to at least one indicator of coronary artery disease, and a controller that is configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease. The limitations regarding a plurality of distinct (or different) types of fluorescently labeled tracer molecules are newly added limitation and are addressed above in the grounds for rejection regarding claim 31, which discuss why such limitations are not novel over the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/28/07

ANN YEN LAM
PATENT EXAMINER